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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/635,428	08/06/2003	Balaji Venkataraman	52761-0100 (285976)	7339

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EXAMINER	
PESELEV, ELLI	
ART UNIT	**PAPER NUMBER**
1623	

DATE MAILED: 07/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/635,428	VENKATARAMAN, BALAJI	
	Examiner	Art Unit	
	Elli Peselev	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 June 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14,18-22 and 24-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14,18-22 and 24-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 18-22 and 24-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treating or preventing a vascular disease, does not reasonably provide enablement for the treating or preventing dementia. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors regarding undue experimentation have been summarized in In re Wands, 858 F.2d 731, 8 USPQ 1400 (Fed. Circ. 1988) as follows:

(1) The quantity of experimentation necessary (time and expense);

It would take an undue amount of experimentation to determine whether the claimed methods are effective in treating and preventing dementia.

(2) The amount of direction or guidance presented;

The instant specification fails to provide any guidance on how to chose a patient in need of prevention of dementia.

(3) The presence or absence of working examples of the invention;

The specification fails to provide any examples directed to the treatment and prevention of dementia.

(4) The nature of the invention;

The invention relates to the treatment and prevention of dementia. However, the treatment and prevention of dementia is not known in the prior art.

(5) The state of the prior art;

The treatment and prevention of dementia with a vitamin composition is not known in the prior art.

(6) The predictability or unpredictability of the art;

The treatment and prevention of dementia is highly unpredictable since to date there are no known effective methods for the treatment and prevention of dementia.

(7) The breadth of the claims;

The claims encompass the treatment and prevention of all types of dementia and

(8) The relative skill of those skilled in the art.

A person having ordinary skill in the art at the time the instant invention was made would not have able to predict whether the claimed methods are effective in treating and preventing of dementia based on the evidence presented in the specification.

Applicant's arguments filed June 29, 2005 have been considered but have not been found persuasive.

Applicant contends that the terms "treatment and prevention" are defined on pages 13 and 14 of the specification. Said pages have been considered and have been found persuasive with respect to the vascular disease. However, the specification fails to present any evidence that the claimed methods are effective for the treatment or prevention of dementia. The only example set forth in the specification relating to dementia is set forth on page 19 of the specification relating to Patient 6. It is stated that the patient has a history of cardiovascular disease and is given the vitamin

composition in order to retard the course of vascular disease and to prevent or retard the onset of dementia. Note that none of the examples set forth in the specification relate to the treatment of dementia i.e. Patient 6 has a cardiovascular disease and not dementia. Further, no evidence has been provided shown hat the onset of dementia was prevented or retarded. Therefore, the method claims still lack enablement with respect to the treatment and prevention of dementia.

Claims 1-14, 18-22 and 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over the European Patent No. 0 595 005 A1 in view of Shapira (U.S. Patent No. 5,993,866).

The European Patent discloses a composition consisting of vitamin B6, folic acid and vitamin B12 which is useful in lowering homocysteine blood levels (page 4). The European Patent teaches that vitamin B12 may be used in the form of cyanocobalamin or hydroxycobalamin or both (page 6, line 31). The European Patent teaches coadministration of the composition consisting of vitamin B6, folic acid and vitamin B12 with an antioxidant such as vitamin E (page 7, line 2). The only difference between the claimed composition and the prior art composition is the presence of magnesium in the claimed composition. However, since Shapira discloses that magnesium is essential for the vitamin B6 function (column 6, lines 1-20), a person having ordinary skill in the art at the time the instant invention was made would have been motivated to add magnesium to the composition disclosed by the European Patent.

Shapira also teaches hyperhomocysteinemia relates to cardio-vascular disease (column 1, lines 44-46). Therefore, a person having ordinary skill in the art at the time

the instant invention was made would have been motivated to use the vitamin composition consisting of vitamin B6, folic acid, vitamin B12, vitamin E and magnesium for the treatment and prevention of vascular disease.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elli Peselev

ELLI PESELEV
PRIMARY EXAMINER
GROUP 1200